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### **STATUS OF CLAIMS**

Claims 1-29 are pending in the application. Claims 15 and 19-29 have been withdrawn pursuant to a restriction requirement. Thus, claims 1-14 and 16-18 are presently under examination.

### **REMARKS**

#### **Rejection Under 35 U.S.C. § 112, second paragraph**

In the Office Action, the Examiner rejected claim 1 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that the phrase “substantially increase the cumulative release” is not defined by claim 1 and the specification does not provide a standard.

In response, Applicants respectfully traverse the rejection and its accompanying remarks. Support for the phrase “substantially increase the cumulative release” is provided in the specification in paragraph [0026], which states that “[b]y substantial increase is meant that an increase of at least 10%.” Having thus been described in the specification, Applicants state that the term is properly defined in the specification and respectfully request that the Examiner reconsider and withdraw the rejection under 112, second paragraph.

#### **Provisional Double Patenting Rejection**

In the Office Action, the Examiner rejected claims 1-14 and 16-18 on the ground of non-statutory obviousness-type double patenting as unpatentable over claims 1-23 of U.S. Patent Application No. 10/894,400, claims 1-14 and 16-18 of U.S. Patent Application No. 10/632,008 and claims 1-14 and 16-18 of U.S. Patent Application No. 10/409,358.

In response, Applicants respectfully traverse the non-statutory obviousness-type double patenting rejection and its accompanying remarks. Applicants also respectfully state that the instant double patenting rejections will be addressed if and when the “provisional” non-statutory obviousness-type double patenting rejection in each application is the only rejection remaining in that application. Pursuant to MPEP 804 I B,

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*If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.*

Thus, since the co-pending applications have not issued as patents and the claims may be amended in the future, Applicants respectfully exercise their right to address the provisional rejections at a future date, if and when the cited applications are issued as patents.

**Rejection Under 35 U.S.C. § 102(b)**

Claims 1 and 4-9 were rejected as being anticipated by Phan et al. (U.S. Pat. No. 5,674,242). Specifically, the Examiner asserts that Phan et al. discloses an "endoprosthetic device, or stent, for the insertion at a vascular site where the stent comprises a polymer and a therapeutic compound...which may be an antiproliferative agent." The Examiner also asserts that "Importantly, Phan et al. also teach that the polymer used is a heat-sensitive polymer and in particular, a methacrylate-containing or an acrylate-containing polymer....*Phan et al. also teach that the crosslinking occurs by exposure to UV light, high energy electrons, and gamma radiation...As such, irradiation is considered an inherent property of the stent of the present invention.*" (emphasis added).

In response, Applicants respectfully traverse the rejection and their accompanying remarks. Phan et al. does not teach all of the elements of the claims, either explicitly or inherently. For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Applicants state that Phan et al. fails as an anticipatory reference because it fails to teach all of the claimed elements of the present invention within the four corners of the reference. The invention of claim 1, as amended, is directed to an implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric release region further comprising a

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polymer, wherein said polymeric release region is treated with a radiation dose that is effective to substantially increase the cumulative release of said therapeutic agent subsequent to administration to a patient by causing a decrease in a weight-average or number-average molecular weight of the polymer.

Phan et al. does not teach irradiating a polymer to increase the cumulative release of the therapeutic agent from the device. Phan et al. also does not teach that the irradiation causes a decrease in a weight-average or number-average molecular weight of the polymer. As stated by the Examiner, "Phan et al. also teach that the crosslinking occurs by exposure to UV light, high energy electrons, and gamma radiation (Col. 6, lines 27-33; see also Example 2 at Col. 12-13). As such, irradiation is considered an inherent property of the stent of the present invention."

Applicants acknowledge that radiation induces changes in polymers. However, whereas the Examiner asserts that Phan et al. teaches *crosslinking by exposure to UV light*, Applicants invention is directed administration of radiation to induce to cause a decrease in a weight-average or number-average molecular weight of the polymer. Indeed, as explained by Applicants in the description, not all polymers are alike.

While not wishing to be bound by theory, when polymers are exposed to radiation, at least two reactions are believed to occur; (1) chain scission (i.e., a random rupturing of bonds) of polymer molecules and (2) cross-linking of polymer molecules. Crosslinking generally results in the formation of larger, three-dimensional polymer structures. Chain scission, on the other hand, generally results in a decrease in the molecular weight of the polymer molecules. While polymers may display both types of reactions, one type of reaction will typically dominate. For increased release, it is preferred to use polymers in which chain scission reactions dominate. Chain scission is generally evidenced by a reduction in the molecular weight of the polymer (e.g., the weight-average or number-average molecular weight of the polymer) upon exposure to the radiation." (paragraph [0030]).

There is simply no teaching or suggestion in Phan et al. of polymers in which radiation is used to increase release of a therapeutic agent from a polymer. In addition, there is simply no teaching or suggestion in Phan et al. that radiation will cause a reduction in the molecular weight of the polymers of Phan et al. by administration of a radiation dose to the polymers. In contrast,

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Phan et al. discusses application of radiation in the context of *crosslinking the polymer* by exposure to UV light, high energy electrons, gamma radiation or heat (*see* col. 6, lines 27-32). Applicants state that such cross-linking does *not* cause the claimed decrease in a weight-average or number-average molecular weight of the polymer.

Further, there is no evidence to support the Examiner's assertion that "irradiation is considered an inherent property of the stent of the present invention." Applicants state that irradiation is not an inherent property of the stent. Rather, irradiation is a type of energy that, when applied to polymers, can induce a change in polymers. The Examiner has offered no evidence to show that the polymers of Phan et al. will be induced by radiation to cause both (1) a substantial increase in the cumulative release of a therapeutic agent or (2) reduction in a weight-average or number-average molecular weight of the polymer.

A holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one. The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted); MPEP 2112 IV.

Based upon Examiner's own characterization of Phan et al. and her statements that crosslinking occurs in the polymers of Phan et al. upon radiation, Applicants state that a holding of inherency cannot flow as a necessary conclusion and instead, teaches away from such a finding. Thus, Applicants submit that inherency has not been shown and respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 102(b).

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Claim 1 is the sole independent claim, and the above comments apply directly to this claim. All other rejected claims 4-9 are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above.

Rejection under 35 U.S.C. §103(a)

In the Office Action, the Examiner has rejected claims 10-14 and 16-18 under 35 U.S.C. 103(a) as being obvious over Phan et al. in view of Pinchuk (U.S. Pub. No. 2002/0107330) in further view of Furst (U.S. Pub. No. 2002/0099438). Claims 2-3 are rejected as being obvious over Phan et al. in view of Cruise (U.S. Pub. No. 6,537,569).

In response, Applicants respectfully traverse the rejections and their supporting remarks. Applicants state that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants state that the rejection fails at least because of the fundamental defects discussed above with respect to independent claim 1 and these defects are not remedied by the secondary references. The prior art references, in combination, fail to teach or suggest all the claim limitations. As indicated above with respect to the anticipatory rejection over Phan et al., Phan et al. fails to teach all of the claimed features. Neither of the secondary references, Furst or Cruise, remedies these deficiencies. As such, the Examiner has not established that the combined references teach or suggest all of the claimed features.

For at least these reasons, Applicants respectfully submit that claims 10-14 and 16-18 are patentable over the cited references.

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For at least these reasons, Applicants respectfully submit that claims 10-14 and 16-18 are patentable over the cited references.

### CONCLUSION

Applicants submit Claims 1-14 and 16-18 are in condition for examination, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicants' attorney at (908) 518-7700 in order that any outstanding issues be resolved.

### FEES

The Examiner is authorized to charge the petition fee for a three-month extension of time and any other fees deemed to be owing for this application to Deposit Account Number 50-1047.

Respectfully submitted,



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